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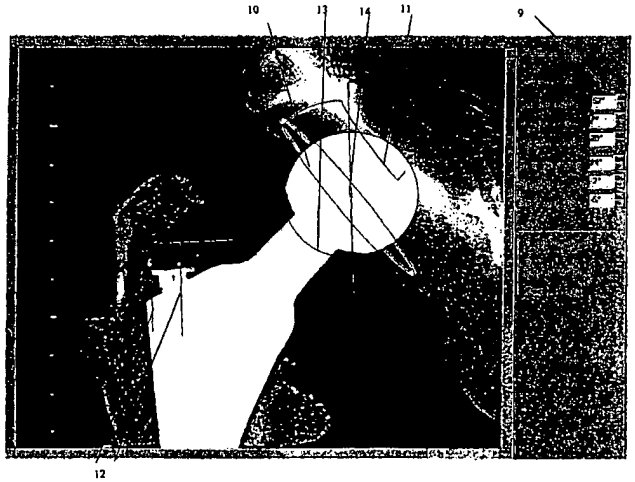
(54) Title: METHOD AND DEVICE FOR PROVIDING OF INFORMATION AFTER INSERTION OF A PROSTHESIS IN A HIP-JOINT



(57) Abstract: Method and device for providing of information after inserting of a prosthesis in a hip joint comprising prosthesis tem (7) and a prosthesis cup (1) and based on this information the position of the components of a hip prosthesis is provided. The prosthesis stem (7) and the prosthesis cup (1), or the part of the body in which the prosthesis are provide are provided with markers (2, 3, 4, 8, 8') that are shown on a X-ray picture. The X-ray picture is downloaded in a image-processing program wherein assistance lines (10, 11, 13, 14, 12), in order to determine the position of the prosthesis components, is downloaded manual or automatic in the image-processing program and the assistance lines (10, 11, 13, 14, 12) is brought in coincidence with the images of the markers on the X-ray picture. Thereater are the angels respectively for the prosthesis components by a calculation unit in the image-processing unit.

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METHOD AND DEVICE FOR PROVIDING INFORMATION AFTER INSERTION OF A PROSTHESIS IN A HIP JOINT

The present invention regards a method of and device for providing information regarding the result of inserting a prosthesis in a hip joint, and on the basis of this information indicate the position of the components of a femoral prosthesis, in order to be able to advise a patient with regard to what movements can be carried out without risking the prosthesis dislocating (luxating), and more particularly of the type stated in the preamble of Claim 1 and Claim 2.

A femoral prosthesis consists of two main components, a prosthesis stem (the femoral component) and a cup (the acetabulum component). At one end, the prosthesis stem is provided either with a spherical condyle or a prosthesis neck on which may be placed a condyle, where the condyle is designed for close, sliding accommodation in a spherical depression in the cup. Together, the prosthesis stem with the condyle and the cup will act as a ball and socket joint to replace the natural hip joint.

The other end of the prosthesis stem comprises an elongated part adapted to be attached to the hollowed femoral canal in the patient's femur.

The cup is adapted to be attached to the joint cavity on the patient's pelvis. The hemispherical depression in the cup is via a side face connected to an outer surface adapted to be attached to the pelvis. The outer surface may have various shapes, depending on how it is to be attached to the pelvis and any other choices made by the supplier. Many cups are shaped as an approximate hemisphere, where the outer surface of the hemisphere is adapted to be attached in the pelvis. The side face connecting the depression and the outer surface may be flat or optionally slope in towards the depression, which is preferably approximately central in the side face.

The prosthesis stem and the cup may be fixed to the femur and the pelvis, respectively, by use of acrylic cement or by a cement-less force fit.

When replacing a worn out hip joint with a prosthesis, the femur head is replaced by the upper femur being cut and the femoral canal of the femur being hollowed out at the top in order to give room for the elongated prosthesis stem, which is either cemented into the femoral canal or force fitted.

The cavity on the pelvis is milled out to receive the cup, which is then fixed either by means of cement or a force fit.

If the condyle of the prosthesis is detachable, this is placed on the prosthesis stem before the condyle is placed in the cup; the joint is assembled by lifting the patient's leg up to a natural position and inserting the condyle in the hollow of the cup, whereupon the incision is closed.

Such a prosthesis should give the patient a mobility that approximates that which is provided by the natural joint. However, as the joint capsule etc. is weakened or possibly removed during surgery, it becomes possible for the patient to move the operated leg into positions that are outside of the natural mobility. This may cause the condyle to jump out of the cup (luxation). Moreover, it is important that a "natural" movement of the joint does not cause the patient to get in a situation in which the leg ends up in positions where the neck of the prosthesis rides on the edge of the cup, as this may cause luxation. This happens through simple leverage. Luxation occurs in the case of between 2 and 9% of all patients who have had a femoral prosthesis put in. If this happens, the patient must be anaesthetised before the joint is put back into place. Some patients must have a new operation. The risk of luxation is much greater in patients whose prosthesis components are assembled so as to have an incorrect mutual positioning, than in those where the mutual positioning of the components is correct, as incorrectly assembled prosthesis components may result in the leverage effect as described above.

The present invention aims to provide a tool that makes it easier for the surgeon, following a prosthesis operation, to form a picture of the positioning of the prosthesis components, and thereby any tendency towards luxation. In possession of such

information, the surgeon may after surgery give patients individual advice regarding which movements the new prosthesis joint will allow without risk of the prosthesis dislocating.

In orthopaedic publications, it is opined that an optimum mutual relationship between the prosthesis stem and the cup results in a reduced risk of luxation because the patient can go through the everyday natural range of motion (ROM) without the parts of the prosthesis ending up in such mutual positioning so as to entail a risk of luxation.

The inventor has previously, in experimental studies, shown (not published) that the most expedient ROM is achieved by assembling both prosthesis components in a manner so as to give them a forward angle of about 15 degrees relative to the frontal plane of the body, while the cup forms an angle of 45 degrees with the horizontal plane. In medical terminology, forward angling is termed anteversion.

The inventor has also previously shown (not published) that even though the optimum is to have each of the components angled forwards at 15 degrees, the result is almost as good if the sum of the forward angling of the two components is 30 degrees. Thus a prosthesis joint where the cup is angled forwards at 5 degrees and the prosthesis stem is angled forwards at 25 degrees will result in an ROM for the patient that is nearly as expedient as if both components were angled forward at 15 degrees, the sum of the forward angling is both cases being 30 degrees.

In a previous application, the inventor has described methods and devices for ensuring the above mentioned correct positioning of the prosthesis components. However it is desirable, regardless of the method used, to be able to perform a quality check on the position of the prosthesis components, which moreover allows individual counselling of the patient with regard to which movements are considered detrimental.

This is provided through a method and device of the type mentioned by way of introduction, the characteristics of which appear from Claim 1 and Claim 2, respectively, further characteristics appearing from the remaining dependent claims.

In the following, the invention will be described in greater detail with reference to the drawings, in which:

Fig. 1 shows the pelvic components (the cup) with a potential design of markers for known prosthesis positions;

Fig. 2 shows the femoral component (the prosthesis stem) with a design of markers for known positions relative to the geometry of the prosthesis;

Fig. 3 shows an alternative for fixing the patient's feet in a standardised and reproducible position when taking X-rays;

Fig. 4 shows an example of an X-ray following an operation; and

Fig. 5 shows the display of a programme for determining the position of the prosthesis after an operation.

In order to be able to see the position of a femoral prosthesis on an X-ray, or for an image processing system to be able to determine the position of the femoral prosthesis, markers are required on, or in a known relation to, the various prosthesis components.

Figs. 1 and 2 show examples of markers arranged on the pelvic component (the cup) and the femoral component (the prosthesis stem), respectively. Fig. 1 shows metal (wire) elements 2, 4, 3 of a known length and shape arranged on the outside of the prosthesis (the cup) 1. In the example shown, the wire element is an elongated wire arranged as a hook 2 in part of the periphery of the upper portion of the cup, which continues in a part 4 that extends in a perpendicular direction to the periphery, and which at the lower portion of the cup extends across the entire periphery 3. The cup, which is normally made from a plastic material, is not visible in on X-ray, and as such the metal wire will appear in full on the X-ray despite the metal wire being attached to the cup e.g. through being covered by the plastic material at certain attachment points.

Figure 4 shows an X-ray of a hip joint with an inserted prosthesis, indicating the markers 2, 3, 4 of the cup. The peripheral portion 3 defines an ellipse that varies from a

line to a circle, depending on the position of the cup. Likewise, the length of the part 2 will vary according to the position of the cup 1.

This description of the invention uses this example of markers; however other forms of markers will be possible, such as those described e.g. in GB 2 134 360.

Another possibility is to drill holes in the cup, where small, X-ray proof markers are provided at known positions in the plastic part of the prosthesis.

Furthermore, metal elements may be provided, which are knocked or drilled into the pelvic bone at a known distance from and angle to the prosthesis. This may be achieved by means of a tool, e.g. a pair of tongs, which grips around the cup after the cup has been positioned and fixed in the joint socket on the pelvis. This tool is shaped so as to only fit the cup in one position. The tool is equipped with one or more guiding channels through which markers or components in which the markers are embedded, are screwed or knocked into the pelvic bone. Using one or more markers attached to the pelvic bone allows the use of standard prosthesis cups that do not require modification in order for the image processing programme to be able to determine the angles of the prosthesis cup in the joint socket on the pelvis. The shape of the marker on the cup and the spatial positioning of the marker disposed in the pelvis will vary on an X-ray in dependence on how the prosthesis cup is positioned in the joint socket on the pelvis.

Fig. 2 shows an example of a marker for the femoral component (the prosthesis stem), which is used in the further description of the invention. Here, balls 8, 8' of tantalum are arranged diagonally across from each other in a plastic sleeve 5 that is screwed to the prosthesis stem 7. The distance between these balls 8, 8' will vary on an X-ray in dependence on the direction in which the prosthesis neck points, whether it points forwards or backwards relative to the transversal plane of the patient (is anteverted or retroverted).

The measurement markers may be fixed to the prosthesis component, as they are screwed to existing or new holes in the prosthesis.

Another possibility is for the measurement markers to be shaped as a short metal or plastic pipe stub (1 to 2 mm) that is fixed to the prosthesis component by the pipe stub being guided down over the prosthesis neck and fixed to the prosthesis neck with a set screw or through spring loading. The pipe stub is provided with X-ray proof markers in a known position relative to the geometry of the prosthesis.

Measurement markers may be mounted by being threaded onto the prosthesis stem from below and fixed by friction or screws. They may also be disposed in a thin plastic or methyl methacrylate tube that is threaded onto the prosthesis stem from below.

It will also be possible to provide metal elements in the actual femoral bone, which are knocked or drilled into the femoral bone at a known distance from and angle relative to the prosthesis. This presuppose the use of a provisional tool that is mounted on the femoral prosthesis (e.g. on the prosthesis neck) and has points of support against other areas of the prosthesis, so as to position the tool in a unique manner on the prosthesis. The tool may be provided with two or more guide channels through which markers are knocked into the femoral bone. Alternatively, it may hold a (plastic) block in which the markers are embedded, while the block is screwed to the bone.

X-rays must be taken under standardised conditions. This is achieved by placing the patient in a reproducible position, through the feet being fixed in special shoes placed on an X-ray table as indicated in Fig. 3. Alternatively, the patient may lie on his back with his legs hanging off the edge of the X-ray table. This is commonly used, as the weight will then set the angle correctly. The patient is placed with his pelvis in the horizontal position, which is checked with a water level resting on the iliac crest (spina iliaca).

As previously mentioned, Fig. 4 shows an X-ray of a hip joint with an inserted prosthesis, where, in addition to the cup markers, markers 8, 8' also appear, and the distance between the markers give a picture of the position of the prosthesis neck. Because the markers 8, 8' (e.g. balls) have been placed diagonally in the plastic sleeve

(plastic block) 5, an increasing distance between the balls 8, 8' on an X-ray file will imply a decreasing anteversion or possibly retroversion, while a decreasing distance between the balls 8, 8' will imply an increasing retroversion, i.e. a short distance means that the prosthesis neck is anteverted, and a great distance means that the prosthesis neck is retroverted.

Based on the X-ray with the markers, the surgeon is therefore able, through manual measurement of the distances and angles, to make a statement regarding the position of the prosthesis. However, such a manual measurement is burdened with potential flaws and a not insignificant measuring uncertainty. Thus an automatic or partly automatic interpretation of the X-ray is desirable. This may be provided through a computer programme that superimposes auxiliary lines 10, 11, 12 (cf. the display in Fig. 5) on the X-ray, which are guided over the respective markers, either manually by an operator for the computer processing equipment or automatically, by identification of the pixel value of the markers, and impose themselves over the markers. When the auxiliary lines have been arranged over the respective markers, a calculating unit in the image processing unit will calculate the angels on the basis of trigonometric principles, determining the number of degrees of anteversion or retroversion. The calculations may also be performed by means of looking up tables of angles that have been found through accurate measurements on models. Thus the surgeon will obtain a result that is reproducible and independent of the individual, and which will provide a statement on the quality of an operation, while allowing the surgeon to advise a patient as to which movements can be made without risking luxation (dislocating the prosthesis).

The image processing unit may be connected to the X-ray department, so that the X-ray may be transmitted directly to the image processing unit as a graphics file or be stored in a memory that may be accessed by the image processing unit, to allow the responsible surgeon to retrieve the X-ray into the image processing unit.

The image processing programme may for instance be used as follows:

The X-ray is retrieved into the programme for calculating the orientation of the prosthesis stem and the cup, cf. Fig 5. Upon retrieval, the programme will request an answer to which hip the calculation is to apply; right or left. The programme can also do this automatically if the X-ray is marked with an indication of side and the programme automatically selects the correct calculation programme on the basis of a pixel recognition function. Further, templates are selected for the above mentioned auxiliary lines for the relevant prosthesis type, cup and prosthesis stem, respectively. The templates will differ from one prosthesis to the next. These may be retrieved and superimposed on the X-ray automatically, based on the patient information that comes with the loading of the X-ray.

Fig. 5 shows a display of the X-ray with superimposed auxiliary lines adjusted and positioned correctly on the X-ray. This positioning may be done manually by operating the keyboard or mouse, e.g. by 15 depressing and holding the respective mouse buttons when the mouse arrow is located over circle 13 and dragging the circle 13 over the head of the prosthesis, or by the operator positioning the mouse arrow at the centre of the head of the prosthesis and clicking on the left mouse button and positioning the mouse arrow on the outer edge of the circular head of the prosthesis and clicking on the right mouse button, whereupon the diameter of the circle 13 is reduced or increased, whereby correction is made for the degree of magnification on the X-ray film. In order to obtain coincidence with the outer edges of the head of the prosthesis, it may be necessary to repeat the process of centring the circle 13.

The auxiliary circle (the ellipse) 10 is then brought to coincide with the marker 3 (compare with Fig. 4, which is an X-ray of an inserted prosthesis). This is done by the operator adjusting the angles indicated on the display for cup inclination (inclination of the ellipse relative to the horizontal plane 10) and anteversion/retroversion (the degree of opening of the ellipse). The auxiliary line 11 is brought to coincide with the marker parts 4 and 2 by adjusting the apex of the cup (anterior posterior). The auxiliary lines 12 are then brought to run approximately vertically through the markers 8 and 8' by adjusting the angles of stem varus, stem extension and stem anteversion (retroversion).

The auxiliary lines 12 are intersected by a line that is to be parallel to an approximately horizontal plane through the markers on the femoral component 12 by correct adjustment of the auxiliary lines. Following this setting of the auxiliary lines, the operator may read the spatial orientation of the prosthesis.

However these processes may, as indicated above, be carried out automatically by the programme, by the image processing part of the programme finding the co-ordinates of the auxiliary lines and positioning them correctly, thereby automatically providing the desired angles and information required by the operator and the surgeon in order to be able to prescribe the correct treatment and to advise the patient as to how to move in order to avoid luxation. An automatic solution would however require quality assurance through an operator approving the programme results.

C l a i m s

1.

A method of controlling prosthesis positions in a body part where the prosthesis comprises a prosthesis stem (7) and a prosthesis cup (1), where a selected number of markers (2, 3, 4, 8, 8') is positioned on or by the prosthesis in a manner so as to appear on an X-ray,

c h a r a c t e r i s e d i n

taking X-rays of the body part with the markers and loading the resulting image into an image processing programme,

manual or automatic definition of a number of auxiliary lines (10, 11, 13, 14, 12) in the image processing programme on the basis of the known mutual geometry of the measurement markers,

comparison and measurement of deviation between the positions of the auxiliary lines (10, 11, 13, 14, 12) and the positions of the markers (2, 3, 4, 8, 8') in the image processing programme,

calculation of the respective angles of the prosthesis components by use of a calculating unit in the image processing unit, and

displaying the values of the respective angles.

2.

An arrangement at an image processing programme for providing information regarding the result of inserting in the hip joint a prosthesis including a prosthesis stem (7) and a prosthesis cup (1), and based on this information give the position of the components of a femoral prosthesis, where the prosthesis stem (7) and the prosthesis cup (1), or the body parts in which the prosthesis components are arranged, are provided with markers (2, 3, 4, 8, 8') that appear on an X-ray, c h a r a c t e r i s e d i n a device for loading the X-ray into an image processing programme, a device for providing auxiliary lines (10, 11, 13, 14, 12) for determining the position of the prosthesis components, that the auxiliary lines (10, 11, 13, 14, 12) are designed to manually or automatically be brought to coincide with the image of the markers on the X-ray, and that the respective angles of the prosthesis components are calculated by

means of a calculating unit in the image processing unit, in order to be displayed on a screen.

3.

An arrangement according to Claim 2, c h a r a c t e r i s e d i n that the markers of the prosthesis stem are balls (8, 8') made from a material that will appear on an X-ray, preferably tantalum material arranged in a plastic sleeves (5) screwed onto the prosthesis stem (7).

4.

An arrangement according to Claims 2-3, c h a r a c t e r i s e d i n that the markers for the prosthesis stem are formed by a short metal or plastic pipe stub that is fixed to the prosthesis component by the pipe stub being guided down over the neck of the prosthesis and fixed to the neck of the prosthesis by a set screw or through spring loading or being guided up over the prosthesis stem, the pipe stub being provided with X-ray proof markers at a known position relative to the geometry of the prosthesis.

5.

An arrangement according to Claims 2-3, c h a r a c t e r i s e d i n that the markers for the prosthesis stem are formed by metal elements being positioned in the actual femoral bone, which markers are knocked or drilled into the femoral bone at a known distance from and angle to the prosthesis.

6.

An arrangement according to Claims 2-3, c h a r a c t e r i s e d i n that the markers for the prosthesis cup are formed by means of a standard marker on the actual prosthesis cup, and that one or more metal elements are placed in the actual pelvic bone, which markers are knocked or drilled into the pelvic bone at a known distance from and angle to the prosthesis cup.

7.

An arrangement according to Claim 2, characterised in that the display unit is designed to display the calculated angles and also indicate whether any retroversion or anteversion exists.

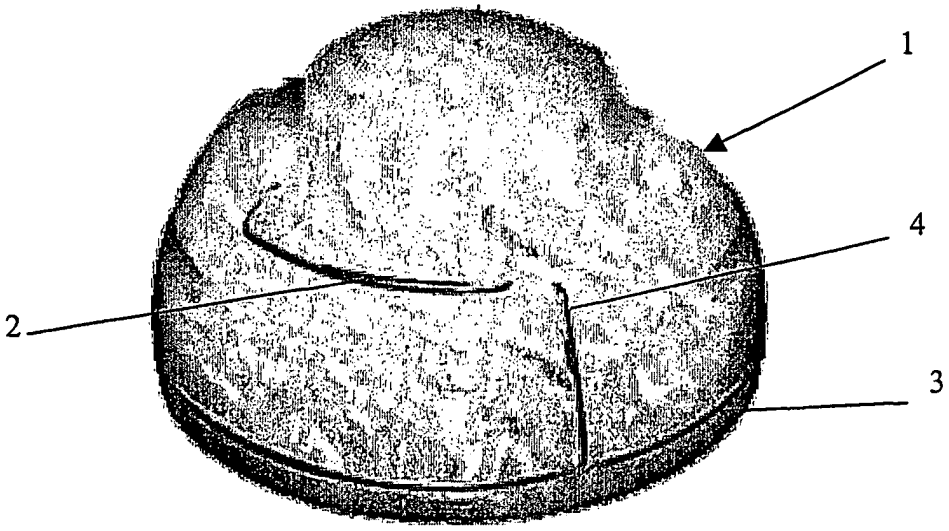

Fig. 1

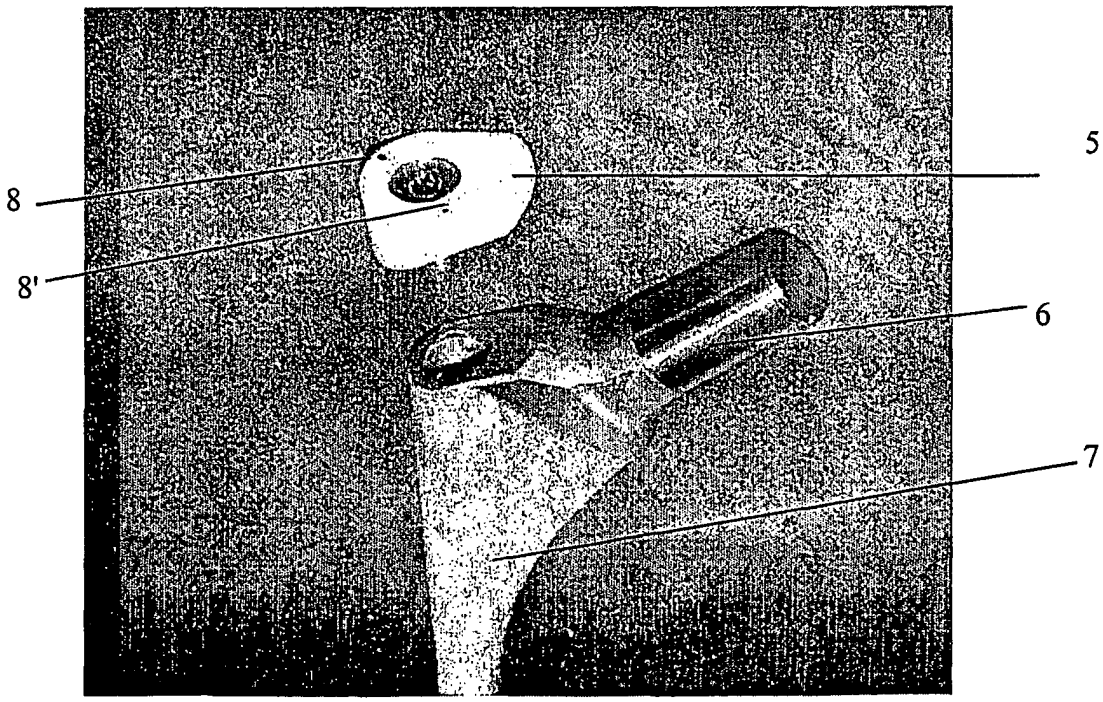

Fig. 2

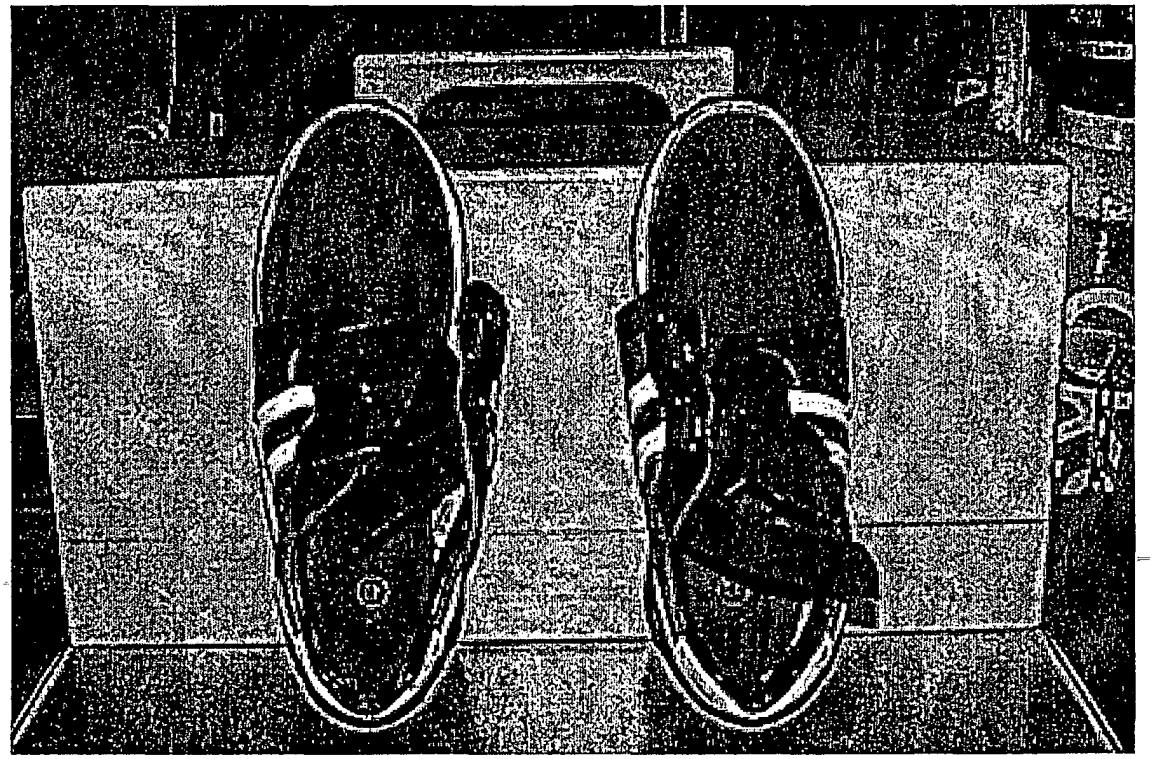

Fig. 3

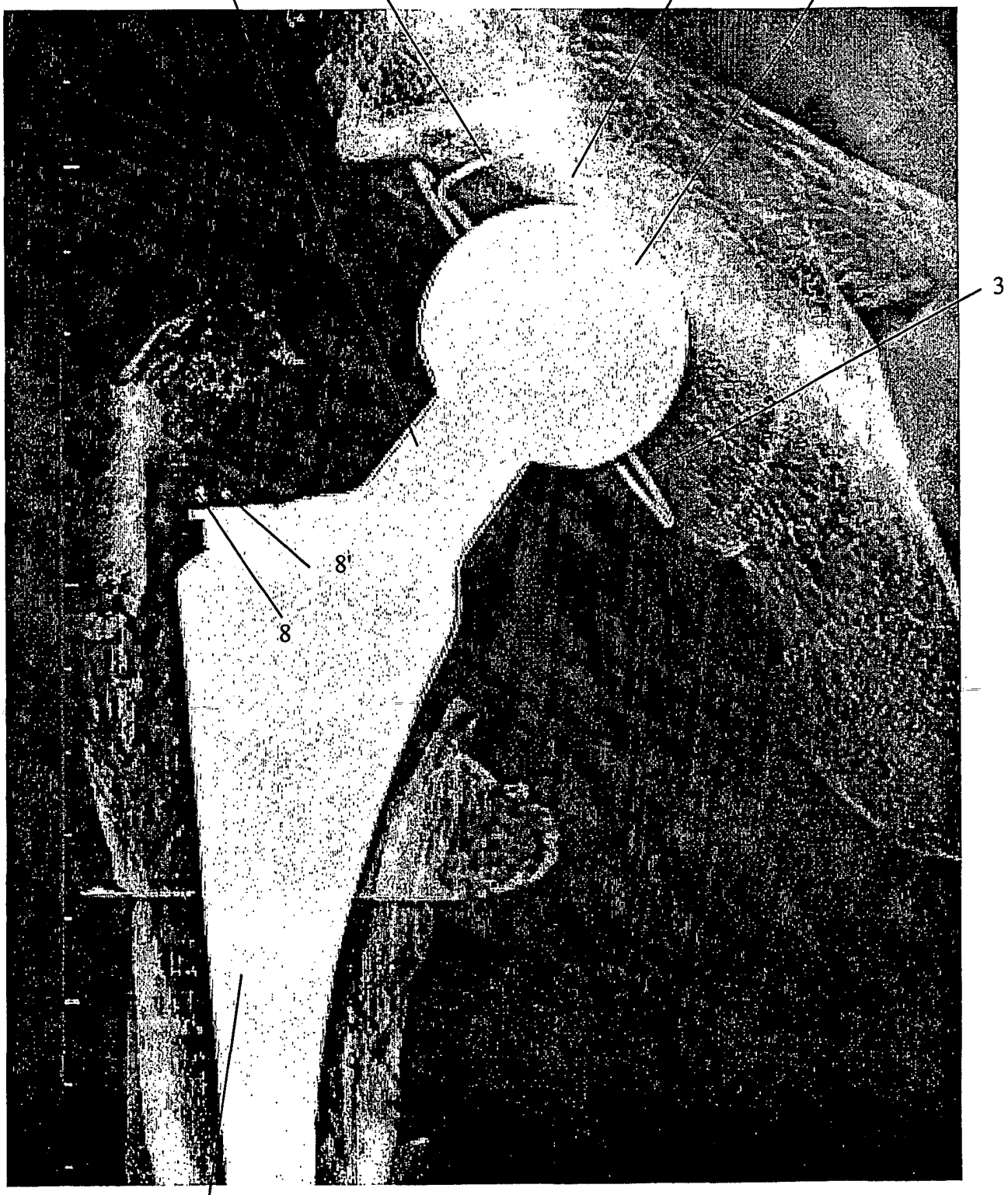

Fig. 4

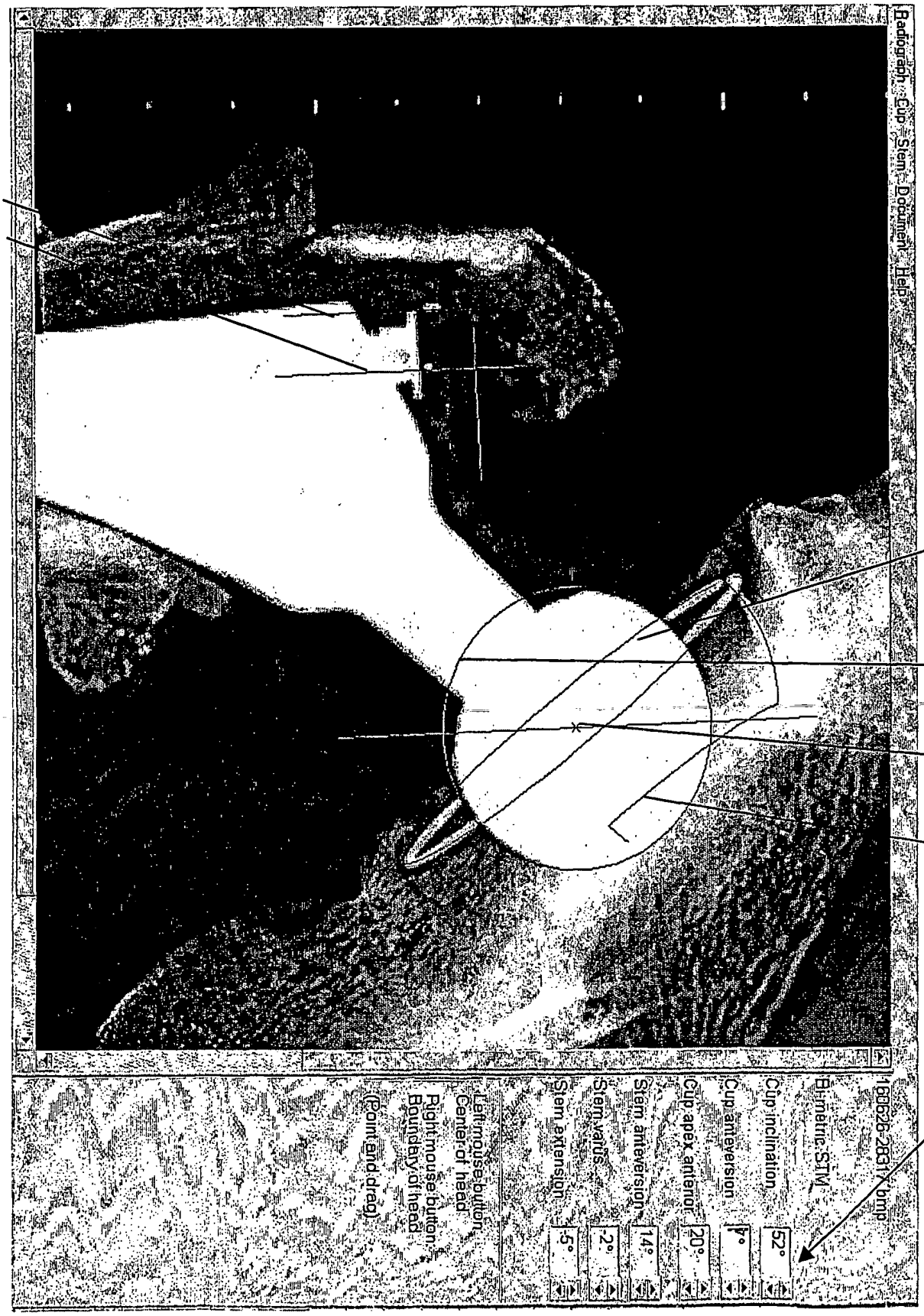
Radiograph Cup Stem Document Help
160626-2831.bmp
Bi-metric STM
Cup inclination
52°
Cup anteversion
4°
Cup apex anterior
20°
Stem anteversion
14°
Stem varus
-2°
Stem extension
-5°
Left mouse button
Center of head
Right mouse button
Boundary of head
(Point and drag)
9
10
11
12
13
14

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 02/00102

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/46, A61B 5/103 // A61B 6/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	FR 2722398 A1 (LANDANGER LANDOS SOCIETE ANONYME), 19 January 1996 (19.01.96) --	1-7
A	US 5405402 A (DONALD W. DYE ET AL), 11 April 1995 (11.04.95) --	1-7
A	US 5799099 A (MATTHEW Y, WANG ET AL), 25 August 1998 (25.08.98) --	1-7

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2002	24 -06- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander/Els Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 02/00102

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

01/05/02

International application No.
PCT/NO 02/00102

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